

REMARKS/ARGUMENTS

This substitute amendment is presented in replacement for the amendment filed March 29, 2006, held non-compliant for failure to properly identify the status of each claim. A petition and fee for a one-month extension of time are attached.

5 In the Action of June 6, 2006, the examiner stated that the status of claims 2-4 and 12 should be changed from "previously amended" to "previously presented", and that the status of claim 16 should be changed from "previously submitted" to "previously presented". Applicant has carefully reviewed the file and determined that claims 2 and 4 *were* previously amended in the paper filed November 1, 2004. Thus, the correct status of claims 2 and 4 is "previously amended", and that status identifier for these claims has not been changed. Claims 3 and 12 were amended in the paper
10 filed April 22, 2005, but that amendment was not entered. Accordingly, the status identifier of claims 3 and 12 has been changed from "previously amended" to "previously presented". The status identifier for claim 16 also has been changed from "previously submitted" to "previously presented", but please see MPEP 714 II (E), which shows the status identifiers previously used by applicant as acceptable alternatives to those listed in 37 CFR 1.121

15 In the Office Action of August 23, 2005, the examiner relied upon the reference to Kurtz, and then modified Kurtz in view of several secondary references (Wilder, Klemow, Gordon, and Forget) to provide Kurtz with structure and function intended to meet the terms of the invention claimed in the present application. Applicant submits that Kurtz does not teach the basic invention, and modification of it in view of the secondary references not only would not produce the claimed
20 invention but would destroy the invention of Kurtz. The device of Kurtz is an absorbent surgical dressing designed for placement about a single tube at the point of entry of the tube into the body of a patient to hold the tube in place. The device of the invention, on the other hand, is a holder adapted to be positioned about several lines of tubing to hold the lines of tubing in separate and organized relationship and prevent them from becoming mixed up during use. The Kurtz device and applicant's
25 device are thus designed for entirely different purposes and have entirely different constructions and functions. Piecemeal reconstruction of Kurtz to vary the number of openings, and/or to alter the shape of the slits and/or the openings would not convert the surgical dressing of Kurtz into an IV line holder as claimed. Not only would the claimed structure not be produced by such modification, but the inventive concept would be lacking. See the more detailed discussion below.

The present invention addresses the problem frequently encountered in the medical profession when treatment of a patient requires the simultaneous use of multiple separate lines of tubing to inject materials into or remove materials from the patient. Medical professionals must exercise great care to ensure that the lines do not become crossed or mixed up. This problem is particularly acute in a
5 rushed and chaotic environment, which is not uncommon, and accidental mixing of lines can occur, with potentially deadly results for the patient.

The present invention provides a simple, inexpensive and effective solution to this problem. The invention is a holder and organizer comprising a thin flat piece of material, preferably paperboard or other suitable material having sufficient rigidity and flexibility to function as intended,
10 and provided with at least one foldable wing having a plurality of openings therethrough, with slits leading to the openings and through which lengths of tubing can be inserted for engagement in the openings to hold the lines separated and organized. The holder has a flat portion on which indicia can be placed in registry with the separate lines held thereby, to provide a quick and reliable visual indication of the proper placement and connection of the lines. In a preferred embodiment, two
15 wings are provided on opposite sides of a flat central portion, and the wings are folded downwardly so that the flat central portion is disposed above the lines to ensure that the indicia placed on the flat central portion is not obscured or rendered difficult to read by the lines.

None of the references of record, whether they are considered individually or in combination, disclose or suggest any comparable device or function.

20 Kurtz (3,286,713) is directed to a surgical dressing designed to surround a single tubular object that leaves the body, and particularly to a dressing that protects the entire skin area immediately surrounding the opening through which the tubular device leaves the body. The sheet 4 in Kurtz is made of a suitable absorbent material such as gauze, thin plastic foam sponge, wet strength non-woven fabric, etc., and obviously is intended to have the physical characteristics of a
25 dressing. It does not relate to nor would it function as an IV line holder that holds a plurality of IV lines in separated and organized relationship. It is a dressing material, and is designed to be placed on a tube so that the tube holds the dressing in place, rather than an IV line holder that holds a plurality of lines in separated and organized relationship. Because of its intended use, it is not apparent that providing it with multiple openings, as proposed by the examiner, would have any
30 function, or how multiple openings would even work to hold the dressing or dressings in place.

Moreover, because of its intended use there is no provision for placement of indicia, nor would there be any reason for providing such a structure and function. Further, Kurtz does not suggest a holder having a central portion and opposite bendable wings. In Kurtz, the two panel portions on opposite sides of the fold line 7 appear to be folded into contiguous, parallel relationship with one another (see figure 4).

Wilder (4,606,735) is a medical tubing holder designed to hold and immobilize a single length of tubing at a site. To this end, the tubing holder of Wilder comprises a central portion and a pair of opposite bendable wings with plural openings formed therethrough. The holder is attached to a surface and in turn holds the length of tubing so that the tubing is immobilized and a tug thereon will not dislodge it. There is no suggestion of a holder for holding multiple lengths of tubing to prevent them from becoming mixed up, and for providing indicia to indicate the purpose of each tube. Figure 1 shows Wilder's preferred embodiment, wherein a single opening is provided in each wing, and figure 5 shows an alternate embodiment wherein multiple openings are provided. However, both embodiments are intended to hold a single tube. Obviously, with a single tube, there is no need for indicia, nor is there any suggestion in Wilder of holding a plurality of separate tubes in separated and organized relationship to avoid accidental mixing and mis-connection of the tubes. Wilder was cited for its teaching of placing a plurality of openings side-by-side, and it was the examiner's position that it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kurtz by providing a plurality of openings in the marginal edge of the Kurtz device to support additional lines. However, simply placing a plurality of openings in Kurtz in view of the plural openings found in Wilder would not produce the claimed invention. Moreover, there is no suggestion or motivation in either Wilder or Kurtz for making this proposed modification, and if it were made the Kurtz device likely would be rendered unsuitable for its intended purpose.

Klemow (4,863,020) is directed to a spark plug wire hangar device that permits the display of individual spark plug wires at a point of sale. Individual wire holders are suspended from a rack. This patent was cited for its teaching of a shaped slit having angularly offset portions, and it was the examiner's position that it would have obvious at the time the invention was made to modify the slits in Kurtz by providing them with angularly offset portions to prevent the tubing from slipping out of the opening. However, the slits in Kurtz are arranged so that they extend in different directions when the dressing is operatively folded, whereby the tubing would be prevented from slipping out of the

opening. Thus, there would be no motivation for making the proposed modification, and even if it were made the claimed invention would not result, i.e., the basic reference to Kurtz does not teach or suggest the claimed invention, and modifying the slits as proposed would not result in the claimed structure and function.

5 Gordon (5,573,111) is directed to a paperboard bottle carrier and is in a non-analogous art. Although it does show a device made of paperboard, and short radial slits around the edges of the openings, it is not likely that someone having ordinary skill in the art would look to the bottle carrier art for a solution to problems found in the medical devices art. There simply is no suggestion in this patent of modifying either Wilder or Kurtz. Even if Kurtz were modified in view of Gordon to make
10 the Kurtz device of paperboard, and/or to provide slits around the opening, the structure and function of the presently claimed invention would not be met.

 French patent 2,562,042 to Forget is directed to a package insert for holding a plurality of ampoules in aligned, separated relationship to one another. This patent is concerned with an entirely different problem and contains no suggestion of the presently claimed invention. It was cited for its
15 teaching of providing notches at the outer ends of the slits, and it was the examiner's position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kurtz by providing notches at the outer ends of the slits in view of Forget. However, even if this modification were made, the claimed invention would not result. You would still have a surgical dressing designed and intended to be placed about a single tube where it enters a patient's body to
20 hold the tube in place, and providing notches at the outer ends of the slits would not alter that fact.

 It is respectfully submitted that neither Kurtz, Wilder, Klemow, Gordon nor Forget teach the present invention, whether these patents are considered individually or in combination. There simply is no suggestion or motivation in any of these references for making the proposed modifications in an effort to produce the presently claimed invention, and even if the modifications were made the
25 claimed invention would not result.

 To establish obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when
30 combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the

claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)

5 If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

10 If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, or require a substantial reconstruction and redesign of the elements shown in the primary reference, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 122 USPQ 349 (CCPA 1959).

In view of the above, it is respectfully submitted that the rejection of the claims as obvious over Kurtz modified in view of Wilder, Klemow, Gordon and/or Forget is improper and should be withdrawn and the claims allowed.

Respectfully submitted,
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